[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

PROSPECTIVE GRANT OF EXCLUSIVE LICENSE: Development of Chemopreventive Treatments for Head and Neck Squamous Cell Carcinoma

AGENCY: National Institutes of Health, Public Health Service, HHS

ACTION: Notice

SUMMARY: This is notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR404.7(a)(1)(i), that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive evaluation option license to practice the inventions embodied in PCT Patent Application No. PCT/US2009/054478, U.S. Patent Application No. 13/059,335 and foreign equivalents thereof entitled "Chemopreventive of Head and Neck Squamous Cell Carcinoma" (HHS Ref. No. E-302-2008/0) and PCT Patent Application No. PCT/IL2010/000694, U.S. Patent Application No. 13/391,756 and foreign equivalents thereof entitled "Prevention and Treatment of Oral and Lips Diseases Using Sirolimus and Derivatives Sustained Release Delivery Systems for Local Application to the Oral Cavity" (HHS Ref. No. E-282-2009/0) to Rapamycin Holdings, Inc., which is located in San Antonio, TX. The patent rights in these inventions have been assigned to the United States of America.

The prospective exclusive evaluation option license territory may be worldwide and the field of use may be limited to use of the Licensed Patent Rights for the prevention and treatment of head and neck cancers.

Upon the expiration or termination of the exclusive evaluation option license, Rapamycin Holdings, Inc. will have the exclusive right to execute an exclusive commercialization license which will supersede and replace the exclusive evaluation option license with no greater field of use and territory than granted in the exclusive evaluation option license.

DATE: Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before [Insert date 15 days from date of publication of notice in the FEDERAL REGISTER] will be considered.

ADDRESS: Requests for copies of the patent application, inquiries, comments, and other materials relating to the contemplated exclusive license should be directed to: Whitney A. Hastings, Ph.D., Licensing and Patenting Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Telephone: (301) 451-7337; Facsimile: (301) 402-0220; E-mail: hastingw@mail.nih.gov.

SUPPLEMENTARY INFORMATION: In head and neck squamous cell carcinoma (HNSCC), a cancer occurring mostly in the mouth, it is frequently observed that the Akt/mTOR pathway is abnormally activated. Therefore, inhibiting this signaling pathway

may help in treating this disease. Rapamycin and its analogs are known to inhibit the activity of mTOR so in principle they could serve as therapeutics for treating HNSCC.

This technology describes a method of potentially preventing or treating HNSCC through the inhibition of mTOR activity. The proof of this principle was demonstrated by rapid regression of mouth tumors in mice afflicted with Cowden syndrome with the administration of rapamycin. Like HNSCC, development of this disease is linked to over activation of the Akt/mTOR pathway. Furthermore, the therapeutic potential of rapamycin was demonstrated using mice in experiments that model chronic exposure to tobacco, which promotes the development of HNSCC. Therefore, inhibitors of mTOR have considerable potential in the prevention and treatment of HNSCC. Moreover, using a local, sustained-release oral drug delivery system for early intervention to prevent potentially malignant or premalignant lesions developing into HNSCC, could deliver the inhibitors of mTOR with reduced systemic side effects and a lower required drug dose.

The prospective exclusive license and any further license applications received as objections to this Notice of Intent to Grant an Exclusive License, will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR Part 404.7. The prospective exclusive evaluation option license is being considered under the small business initiative launched on 1 October 2011, and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR Part 404.7. The prospective exclusive evaluation option license, and a subsequent exclusive commercialization license, may be granted unless the NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR Part 404.7 within fifteen (15) days from the date of this published notice. A

previous Notice of Intent to Grant an Exclusive License for the instant technology was published in 77 FR 28614, Tuesday, May 15, 2012.

Complete applications for a license in the field of use filed in response to this notice will be treated as objections to the grant of the contemplated exclusive evaluation option license. Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

October 25, 2012
Date

Richard U. Rodriguez,
Director
Division of Technology Development and Transfer
Office of Technology Transfer
National Institutes of Health

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